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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,118	10/30/2001	Stanford Mark Moran	INT 004.10	8022

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Intarcia Therapeutics, Inc.
ATTN: Barbara G. McClung
24650 Industrial Blvd
Hayward, CA 94545

EXAMINER	
SEHARASEYON, JEGATHEESAN	
ART UNIT	PAPER NUMBER
1647	
MAIL DATE	DELIVERY MODE
05/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/004,118	MORAN, STANFORD MARK	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon, Ph.D	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *87,88,90-96 and 98-114* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *87,88,90-96 and 98-114* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/28/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to Applicant' response and amendments filed 1/28/2008. Claims 86-113 were pending in the application. Claims 86, 89 and 97 have been cancelled. Applicant has amended claims 90, 91, 93, 95, 98 and 103-107. Applicant has added new claim 114. Thus, claims 87, 88, 90-96 and 98-114 are pending and examined.

2. Any objection or rejection of record, which is not expressly repeated in this action, has been overcome by Applicant's response (including amendments) and withdrawn.

Information Disclosure Statement

3. The information disclosure statement submitted on 1/28/2008 has been fully considered.

Claim Rejections - 35 USC § 103, maintained

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4a. The rejection of claims 87, 88, 90-96 and 98-114 (114 new claim) under 35 U.S.C. 103(a) as being unpatentable over Parker *et al* (WO 00/40273 – cited in the IDS received on 5/31/2007) in view of Goeddel *et al* (US 5,120,832), and further in view of Theeuwes *et al* (US 4,976,966) is maintained for reasons set forth in the Office Action mailed 8/27/2007 pages 3-6.

The claims of the instant invention are drawn to a method of treating hepatitis C virus (HCV) infection in a subject in need thereof, comprising administering a therapeutically effective amount of omega IFN to the subject. The claims are further drawn to administering various dosage ranges of omega IFN, various routes of administration, and administration of omega IFN via a device such as an implanted osmotic pump.

In the response received on 1/28/2008, the Applicant discusses the legal basis for obviousness rejection (see pages 4-5). The Applicant argues that the claimed invention is not obvious because the claimed combination of references does not each all of the elements of independent claim 87, 88 and 114. Specifically, it is asserted that the references do not teach the administration of IFN-ω protein for treatment of hepatitis C (HCV) infection, do not teach the IFN-ω dosages recited in the claims, and do not teach that IFN-ω is effective in treating HCV. The Applicant also argues the cited combination of art teaches away from the instant invention because Parker teaches administration of a polynucleotide encoding IFN-ω, rather than administration of IFN-ω protein. Finally, the Applicant asserts that the claims are not obvious because the advantages of the present invention, specifically administration of IFN-ω protein and effective treatment of HCV which was resistant to IFN-α treatment, was not recognized in the prior art (secondary considerations).

These arguments have been fully considered but are not persuasive. The combination of Parker and Goeddel teaches a person of ordinary skill in art that HCV infection can be treated by administration of a polynucleotide encoding IFN-ω, and IFN-

ω polypeptides capable of mediating antiviral immunity, respectively. Although Parker teaches administration of a polynucleotide encoding IFN-ω, a person of ordinary skill in the art would expect that this administered polynucleotide would be expressed and translated into IFN-ω protein, and that this polynucleotide-encoded IFN-ω protein would be effective in treating HCV infection. Furthermore, the disclosure of Goeddel provides the skilled artisan with such an IFN-ω protein. Thus, a person of ordinary skill in the art would find the motivation to treat HCV infection by administering IFN-ω to a person in need of treatment because Parker teaches HCV infection can be treated by IFN-ω, and Goeddel teaches IFN-ω proteins with biological activities, such as antiviral activity, that are similar to the IFN-α that is also used to treat HCV. Furthermore, the utility of the implantable, osmotic pump disclosed by Theeuwes would be apparent to a skilled artisan, who would recognize that administration of IFN-ω using the pump of Theeuwes would result in long-term, sustained administration of IFN-ω proteins, and would overcome the drug-delivery problem associated with administration of proteins, as discussed by Parker and cited by the Applicant in the response received on 1/28/2008. Therefore, the combined teachings of Parker, Goeddel, and Theeuwes provide a person of ordinary skill in the art with the motivation to treat HCV infection by administering the IFN-ω protein of Goeddel using the implantable osmotic pump of Theeuwes.

In response to Applicant's arguments that the cited combination of art does not teach the recited IFN-ω doses, it is noted that as discussed *supra,* Parker, Goeddel, and Theeuwes provides the motivation to treat HCV infection by administering IFN-ω via an osmotic, implantable pump. Since, the general conditions of the invention are

obvious in view of the prior art, it is not inventive to determine optimum or workable ranges by routine optimization. In this case, the combination of Parker, Goeddel, and Theeuwes provides the motivation to administer IFN-ω protein to a person infected with HCV, and a person of ordinary skill in the art, in this case a physician experienced in treating HCV infection, would be able to determine the most effective dosage needed to treat a patient. Furthermore, Parker teaches that the polynucleotide encoding IFN-ω is capable of providing increased serum levels of IFN-ω protein. Since, Parker reference teaches that HCV infection can be treated with a polynucleotide encoding IFN-ω, in the absence of evidence to the contrary, the polynucleotide of Parker would be expected to be expressed and translated into a therapeutically effective amount of IFN-ω, and this dose of IFN-ω would be expected to fall within the claimed dose ranges, otherwise the treatment of Parker would not be effective. Thus, without a clear showing that expression of the polynucleotide of Parker in a subject in need would not produce serum levels of IFN-ω protein within the claimed dosage ranges, one of ordinary skill in the art would expect that the IFN-ω expressed and translated from Parker's polynucleotide would meet the limitations of the instant claims.

Finally, it is noted that Goeddel teaches that IFN-ω proteins exhibit biological activities, including antiviral activity that overlap with or are similar to other type I IFNs, such as IFN-α. Thus, one of ordinary skill in the art would expect that IFN-ω would exhibit anti-HCV activity in the same manner as IFN-α. Furthermore, because the combination of Parker and Goeddel suggest treatment of HCV infection by

administration of IFN-ω proteins, a person of ordinary skill in the art would be motivated to administer IFN-ω in cases where IFN-α has not been effective. It is noted that the instant claims are not drawn to a method of treatment where IFN-α has not been effective. Therefore, claims 87, 88, 90-96 and 98-114 (114 new claim) remain rejected under 35 U.S.C. 103(a) as being unpatentable over Parker *et al* (WO 00/40273 – cited in the IDS received on 5/31/2007) in view of Goeddel *et al* (US 5,120,832), and further in view of Theeuwes *et al* (US 4,976,966).

4b. The rejection of claims 87, 98, 103 and 109-113 under 35 U.S.C. 103(a) as being unpatentable over Parker *et al* (WO 00/40273 – cited in the IDS received on 5/31/2007) in view of Goeddel *et al* (US 5,120,832), and further in view of Theeuwes *et al* (US 4,976,966) and Guillen *et al*. (US 6, 074, 673) is maintained for reasons set forth in the Office Action mailed 8/27/2007 pages 6-7.

The claims of the instant invention are drawn to a method of treating hepatitis C virus (HCV) infection in a subject in need thereof, comprising administering a therapeutically effective amount of omega IFN to the subject. The claims are further drawn to administering various dosage ranges of omega IFN, various routes of administration, and administration of omega IFN via devices such as an implanted osmotic pump and kits.

Applicant, in the response received on 1/28/2008, has cancelled claims 86, 89 and 97. It is argued that since claims 103 and 109-113 are depend on claim 86 the cancellation of claim 86 obviates this rejection. In addition, Applicant asserts that the combination of references do not teach the instant invention because the primary

reference teaches away from the present invention. Thus, it is claimed that the Office has failed to establish a case of *prima facie* obviousness for independent claims 87, 88 and 114.

These arguments have been fully considered and are not persuasive. The teachings of Parker, Goeddel, and Theeuwes have been discussed above in 4a. Guillen *et al.* reference was included in the rejection to teach kits. Claims 98, 103 and 109-113 are now dependent on claim 87 which is rejected as being obvious over Parker, Goeddel, Theeuwes and Guillen. Therefore, claims 87, 98, 103 and 109-113 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Parker *et al* (WO 00/40273 – cited in the IDS received on 5/31/2007) in view of Goeddel *et al* (US 5,120,832), and further in view of Theeuwes *et al* (US 4,976,966) and Guillen *et al.* (US 6, 074, 673).

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5a. The provisional rejection of claims 87, 88, 90-96, 98-108 and 114 (114 new) on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 65 and 86-104 of copending Application No. 10/982,532 is maintained for reasons set forth in the Office Action mailed 8/27/2007 page 8. Applicant requests that the Office hold the rejection in abeyance.

5b. Claims 87, 88, 90-96, 98-108 and 114 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5-7, 17-22, 25 and 40-55 of copending Application No. 11/811,415. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant invention and those of the '415 application are both drawn to methods of treating an immunologic, proliferative, or infectious disease in a warm-blooded animal by administration of IFN-ω protein. Because the '415 application cites treatment warm-blooded animal, including humans, wherein the infectious disease may be hepatitis C, the patient population of the instant application and that of the '415 application overlap. Therefore, it would be obvious to one of ordinary skill in the art that the instant application and the '415 application are variants of each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

6. No claims are allowable.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao, Ph. D can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christine J Saoud/
Primary Examiner, Art Unit 1647

JS
Art Unit 1647.
May 26, 2008.